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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,869

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Hubert Jansen

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,869	<b>Applicant(s)</b> JANSEN ET AL.	
	<b>Examiner</b> PHILIP WIEST	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/07 has been entered.

### ***Response to Amendment***

In the response filed 11/14/07, applicant amended claims 12 and 31 and added new claim 34. Claims 12-34 are currently pending.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "wherein a distance between a base of the sealing portion and an end of the sealing portion on the piercing mandrel is less than the length between the base of the sealing portion and a lower surface of the elastic

stopper within the container" is unclear because it does not define which end of the sealing portion is being referenced. The examiner recommends that this claim be amended to recite "a ***distal*** end" of the sealing portion.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 12-19, 21-23, 26-29, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault et al. (US 2002/0121496) in view of Niedospial (US 5,895,383).

3. With respect to claims 12, 14, 15-18, 19, and 21-23, Thiebault et al. discloses a fluid transfer set comprising a lid portion (44) and an edge portion (50) forming a receiving cap (20). Thiebault further discloses a piercing mandrel (92) that includes a sealing portion and a piercing portion (84), which is configured to pierce the elastic stopper. The piercing mandrel is *fully capable* of piercing the elastic stopper while bead is being disposed in the space if the operator presses the piercing mandrel downward at the same time. The piercing mandrel also comprises a flow channel configured to convey fluid away from the container. Thiebault further discloses an elastic stopper (36) whose edge portion is configured to center the bead within the space, and a sealing

portion (52, 82 and 86) with a greater diameter than that of the piercing portion (84).

The transition between the piercing portion 84 and the sealing portion 82 is substantially stepless. The sealing portion is configured to contact the elastic stopper when the bead is substantially disposed in the space. When a beaded bottle (22) is substantially disposed in the space, the piercing mandrel (84) is configured to pierce the elastic stopper (36), as per claim 16. In addition, the edge portion of the transfer device (50) includes an inward projection (46a) capable of engaging the behind portion of the bead (26), as per claim 17. The transfer device further comprises a central longitudinal axis, as per claim 13, as shown in Figures 3-5. Thiebault et al., however, does not specifically disclose that the sealing portion is formed integrally with and extending from the lid portion, such that the distance between the base of the sealing portion and the distal end of the sealing portion on the piercing mandrel is less than the length between the base of the sealing portion and the lower surface of the elastic stopper within the container.

Niedospial discloses a medicament container closure having a recessed integral spike. The spike comprises a piercing portion 116 and a sealing portion (above annular groove 113) that are formed integrally with a lid portion 118. The sealing portion (above section 113) extends downward such that it creates a seal at the top of the stopper (while not extending to the bottom of the stopper), thereby preventing fluid from leaking out of the container (see Figure 8). Additionally, the width of the piercing mandrel is stepped (at section 113) as it transitions from the piercing portion to the sealing portion, as per Claims 14 and 15. When the bead of a vial is inserted into the interior space, the

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sealing portion contacts the top of the elastic stopper at substantially the same time as the inward projection engages the bead, therefore creating a seal at the exact time that the piercing portion penetrates the bottom portion of the seal. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer set having a cylindrical piercing member of Thiebault et al. with the use of an integral sealing member of Niedospial in order to prevent fluids from leaking through the elastic stopper around the outside of the piercing mandrel, thereby preventing leaks and ensuring the sterility of the fluid.

4. With respect to Claim 13, Thiebault discloses that the receiving cap includes a symmetrical, longitudinal axis.

5. With respect to Claim 27, Thiebault discloses that the piercing portion 84 of the piercing mandrel is disposed closer to the inward projection 46a than to the lid portion

44. See Figure 1.

6. Claims 12, 13, 15, 19, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wadsworth, Jr. (US 5, 374, 264).

7. With respect to Claims 12 and 13, Wadsworth Jr. discloses a fluid transfer device comprising a lid portion 40 and an edge portion 15 forming a receiving cap, the receiving cap defining a space configured to receive a bead of a container closed by an elastic stopper, the edge portion being configured to center the bead of a container (via

angled walls 13 and ribs 32) within the space when the bead is substantially disposed within the space, and a piercing mandrel 26 connected to the lid portion and projecting into the space. The piercing mandrel 26 includes a piercing portion 23 configured to pierce the elastic stopper while the bead is being disposed in the space. The mandrel further comprises a sealing portion 24 having a diameter greater than the mandrel, the sealing portion being configured to contact the elastic stopper when the bead is substantially disposed in the space (see figure 4), and a flow channel being configured to convey fluid away from the container. The sealing portion 24 is formed integrally with the lid portion 14 and contacts the piercing portion. When a vial is inserted and the stopper is pierced by the piercing portion, the distance between the base of the sealing portion (i.e. at the lid) and the distal end of the sealing portion is less than the length between the base of the sealing portion and the lower surface of the elastic stopper. In other words, the sealing portion contacts the top surface of the stopper, but not the bottom surface, thereby forming a seal that prevents fluid from leaking through the top surface. See Figure 4.

8. Regarding Claim 13, the receiving cap is symmetrical about a central longitudinal axis 34.

9. With respect to Claims 15 and 19, the sealing portion 24 of the mandrel includes an end face (adjacent lid portion 40) that is substantially annular. The annular end face of the sealing portion is connected to the rest of the sealing element, and effectively prevents fluid from flowing around the sides of the mandrel (see Figure 2), as per Claim 19.

10. With respect to Claim 22, the sealing portion 24 is substantially conically shaped and adjoins the piercing portion of the mandrel.

11. With respect to Claims 24 and 25, the piercing mandrel is embedded in and stationary relative to the lid portion

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was



not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault et al. in view of Niedospial, and further in view of Meyer (US 5,358,501). Thiebault et al. and Niedospial teach all the limitations of the parent claims 12, 15, and 19 (see rejection above), but do not teach that the sealing element is an o-ring. Thiebault et al. discloses a round opening between the edge portion and the sealing portion, thus motivating one skilled in the art to include a seal that fits round openings. The use of o-rings for sealing means in medical devices is known in the art. Meyer (5358501) discloses a storage bottle containing a constituent of a medical solution, which employs an o-ring as a sealing element between the two containers. Thus, it would be obvious to one skilled in the art to apply the o-ring of Meyer to the fluid transfer device of Thiebault et al., because doing so will achieve an effective and inexpensive sealing means, thereby preventing the loss of fluid around the edges of the vial.

15. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault et al. in view of Niedospial, and further in view of Zinger et al. (US 6,558,365). Thiebault et al. and Niedospial disclose the device of Claims 12 and 17 substantially as claimed (see rejection above), but do not disclose that the edge portion further comprises a free edge extending away from the inward projection 46a. Zinger et al.

discloses a fluid transfer device comprising an edge portion that has an inward projection that holds the bead of a container in position and a free edge portion 26 extending away from the inward projection in a direction that is substantially parallel to the central axis (see Figure 2). The free edge portion has a larger inner and outer diameter than the rest of the receiving cap 20" and therefore is capable of guiding a container such that it is centered as it is inserted onto the piercing mandrel. It is very important that the mandrel pierces the elastic stopper in the center in order to reduce the chances of the stopper tearing as well as ensure that the neck of the bottle does not impede the mandrel. Furthermore, the use of flanges such as these is well established in the art in order to properly center and secure mandrel over the stopper of a bottle (Column 4, Lines 24-33). Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the fluid transfer device of Thiebault et al. with the outwardly-extending flares of Zinger et al. in order to guide a bottle into the desired position as it is inserted.

### ***Conclusion***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP WIEST whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761  
2/6/08

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761